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PATENT 4845-0101PUS1

#### IN THE U.S. PATENT AND TRADEMARK OFFICE

In re Patent Application of: Thomas L. Haschen et al.

Application No.: 10/530,390

Confirmation No.: 3643

Filed: June 14, 2005

Art Unit: 1794

For: FERMENTATION BYPRODUCT FEED

Examiner: K. J. Mahafkey

FORMULATION AND PROCESSING

### REPLY BRIEF UNDER 37 C.F.R. § 41.41

## MS Appeal Brief - Patents

Commissioner for Patents P.O. Box 1450 Alexandria, VA 22313-1450

Sir:

As required under § 41.41(a), this Brief is filed within two months of the Examiner's Answer dated April 16, 2008. A request for an oral hearing is also being filed on even date herewith.

The following remarks respond to arguments presented in the Examiner's Answer and are presented in support of the Appeal Brief.

On page 10, the Examiner's Answer indicates that it is unclear in claims 116 and
 122 as to what the starting mixture consists of.

In reply, Appellants respectfully submit that the starting nutrient source mixture consists of by-product solubles and one or more crude protein and/or amino acid content nutrient

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source(s), and the-product solubles are from distillers, brewers or fermenters grains as identified in claim 114.

Specifically, with respect to claim 116, Appellants respectfully submit that a determination of what is in the starting mixture is clear from a reading of claim 115, from which claim 116 depends, and from a reading of subparagraph (a) in the second clause of the body of claim 115.

Specifically, with respect to claim 122, Appellants respectfully submit that a determination of what is in the starting mixture is clear from a reading of claim 119, from which claim 122 depends, and from a reading of the second clause of the body of claim 119.

2. On page 10, the Examiner's Answer, with respect to the issue of "omitting essential elements," improperly summarily dismisses the holding of the Court of Customs and Patent Appeals in *In re Borkowski* (citation presented below, with reference to MPEP §2174), which indicates how to apply the first and second paragraphs of 35 USC §112 to rejection of claims in any patent application, based on the invalid premise that case law from other applications is not identical to the present situation.

Appellants respectfully submit that, while the facts of a given case are relevant to specific fact situations, the holding relied upon by Appellants in the *Borkowski* decision is a general principle of patent law that explains how 35 USC §112, first and second paragraphs apply to all patent applications, regardless of their fact situations.

Furthermore, it is noted that the Examiner's Answer fails to even try to address, let alone distinguish, the facts of Borkowski from the facts of the instant application.

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In this regard, the Manual of Patent Examining Procedure is prime evidence of the applicability of the *Borkowski* decision to all patent applications by stating, in §2174, that if a description or the enabling disclosure of a specification is not commensurate in scope with the subject matter encompassed by a claim, that fact alone does not render the claim imprecise or indefinite or otherwise not in compliance with 35 USC §112, second paragraph; rather, the claim is based on an insufficient disclosure (35 USC §112, first paragraph) and should be rejected on that ground, citing *In re Borkowski*, 422 F.2d 904, 164 USPQ 642 (CCPA 1970).

Appellants respectfully submit that this holding is a general principle of patent law applicable to all applications regardless of their facts, and is fully supported by a number of later decided cases, which state the same principle or corollaries to the general rule stated in Borkowski, and serve as further examples that what is being relied upon by Appellant in the Borkowski decision is not fact specific. In this regard, reference is made to the decision in *In re Ehrreich and Avery*, 200 USPQ 504 (CCPA 1979, which clearly states, as a matter of law, that 35 USC §112 does not permit the Examiner to study applicant's disclosure, formulate a conclusion as to what the examiner regards as the broadest invention supported by the disclosure, and then determine whether the claims are broader than the examiner's conception of what the invention is. Unfortunately, that is exactly what has occurred in this Application.

Further in this regard, Appellants refer the Examiner to the general principle of patent law holding in *In re Smythe and Shamos*, 178 USPQ 279 (CCPA 1973), that claims may be drafted as broadly as the prior art allows and mere omission of claim limitations does not suggest omission of steps or parts. Another way of stating this is found in *In re Johnson and Farnham*, 194 USPQ 187 (CCPA 1977), which concludes that undue breadth of claims is not indefiniteness.

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The Examiner's Answer continues in this vein, on page 11, by indicating that that it is unclear in claim 87 if the nutrient increase is achieved in step (a) of claim 84, step (b) of claim 84, or in some other omitted essential step. In response, Appellant respectfully submits that, as clearly stated in the aforementioned "Johnson and Farnham" decision, it is the function of the specification, not the claims, to set forth the practical limits of the operation of the invention and one does not look to the claims (as is improperly being done in the final rejection) to find out how to practice the invention they define, but to the specification. Looking at the claims and questioning them is not the proper way to reject them under 35 USC §112, second paragraph.

In the paragraph bridging pages 11 and 12, the Examiner's Answer continues to improperly confuse what the CAFC and CCPA have clearly held can be properly placed in issue in a rejection under 35 USC §112, second paragraph and what can properly be placed in issue in a rejection under 35 USC §112, first paragraph, and continues to improperly ignore the general patent law principle set forth by the *Borkowski* decision, and the general corollary principles of patent law set forth by the additional decisions cited above, based on the improper argument that the facts of decisions in other applications are not identical to the situation, and is without merit.

3. The Examiner's Answer, in the last full paragraph on page 12 of the Examiner's Answer, states that Heitritter shows a similar process to that as instantly claimed by Appellant. Unfortunately, showing that a reference is something similar to a claimed invention is not the same as disclosing the claimed invention or rendering obvious the claimed invention. To render obvious a claimed invention, the U.S. Supreme Court has set forth what must be shown in the landmark decision of *Graham v. John Deere*, 383 U.S. 1, 148 USPQ 459 (1966). In Graham, the Supreme Court articulated the following four-part test. First, a decision maker must ascertain the

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scope and content of the prior art, which is the state of knowledge at the time the invention was created. This step is necessary because whether an invention is obvious can only be determined by comparing it to what was known in the relevant technological field. Next, the differences between the prior art and claimed invention are to be assessed. Third, the level of ordinary skill in the art is determined because, in assessing whether an invention is obvious, a decision maker takes the viewpoint of one having ordinary skill in the relevant technological field. Finally, the Court permitted the use of non-technical, secondary considerations to help assess whether the invention is obvious. Such considerations include commercial success, the failure of others in developing the invention, and a need that had been long-felt but unfulfilled prior to the creation of the invention.

By relying on Heitritter as only disclosing something "similar" to the claimed invention, the Office is failing to assess the differences between the claimed invention and the prior art, and incorrectly assuming that the rejection just has to come close to what is being claimed in the sense that what Heitritter discloses is "similar" to what is being claimed.

Additional evidence that the Office is using an incorrect basis for rejecting Appellants' claims is reinforced by the portion of the Examiner's Answer from page 14, line 12 to page 15, line 10, where the closest the Examiner's Answer comes to assessing the differences between the claimed invention and the prior art (including Heitritter) is to conclude that "the steps in the method as taught by Heitritter is substantially the same as the method as instantly claimed." Unfortunately, this falls far short of what is required by the *Graham* decision and clearly does not accurately assess the differences between the prior art and claimed invention. In this regard, in this entire portion of the Examiner's Answer, several positively recited features of the claimed invention are missing, including adjusting the temperature and/or moisture content of nutrient

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sources based on an empirically derived relationship that relates the UIP as a percent of the crude protein to an end product temperature in a predictable and repeatable manner to produce an end product, where a specific empirically derived relationship is specified in the claim. The omission of these positively recited features is this analysis is evidence that the Office has not complied with the requirements of the *Graham* decision and fails to make out a *prima facie* case of unpatentability of the claimed invention

The "steps in the method as taught by Heitritter is substantially the same as the method as instantly claimed" test used in this portion of the Examiner's Answer is quite different from that required by the *Graham* decision, and runs contrary to what is required by the *Graham* decision.

Appellants are providing the following table which highlights differences between the claimed "Haschen et al" invention and Heitritter et al's disclosure, most of which do not appear to have been taken into consideration by the Office in determining whether the claimed invention is patentable.

HASCHEN et al	HEITRITTER et al
Starts with distillers, brewers or fermenters wet spent grain and or solubles.	Starts with oil seed meal.
Adds other protein and/or amino acid sources.	Adds hulls and water.
Formulates wet nutrient mixture to precise levels of crude protein, RUP and amino acids.	Adds hulls and water to oil seed meal. "The purpose of adding hulls to the moist meal feed is to obtain proper fiber/protein feed balance."
The addition of other protein or amino acid sources to distillers, brewers or fermenters wet spent grain or solubles enhances the protein nutrient value of the starting wet products.	The addition of hulls to any oil seed meal actually detracts from the protein nutrient value of the starting material. The hulls are diluents from a protein contain standpoint.
Nutrient mixture goes directly into a drier at 200°F to 1000°F.	Soybean meal plus hulls go into a cooker at 150°F to 220°F then into a drier at 100 to 150.
Accurately predicts amounts of crude protein, RUP, total amino acids, RUP amino acids and post ruminal digestibility of the end product.	Does not predict any quantitative RUP increase. Only discloses that a simple increase in RUP occurs. The next time he does it, he

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·	will have to wait until the process is over to determine what RUP increase will be achieved. Following this disclosure only a qualitative outcome is predictable.
Provides an empirical formula to accurately predict specific values of the RUP/UIP of the end product.  UIP(% of CP)=(End product temperature °F X 0.819) – 107.644	Nothing provided to allow quantitative prediction of RUP of end product.
Using the empirical relationship formula, quantitative amounts of RUP/UIP can be accurately predicted with a statistical significance of P< 0.0003 in the end product by manipulating the end product temperature.	Discloses No means of quantitatively varying RUP in the end product.
Can predictably vary the amount of RUP/UIP of an end product from over 50% and up about 83% of the crude protein.	Single example produces an end product with an increase of UIP/RUP, with no means of predictably varying the quantitative UIP/RUP level.
Can predictably vary the amino acid profile and content of both the crude protein and the RUP.	Can only vary the total level by dilution of the oil seed with hulls. Has no disclosure or concept of predicting the total RUP level, even with simple dilution.

4. On page 12, the Examiner's Answer states that Heitritter, the primary reference used in rejecting Appellants' claims, shows a method by which a prediction of enhancing the nutrient value can be obtained. Unfortunately, no details of how this is accomplished by Heitritter are presented, and the speculative possibility that something can be found in Heitritter does not rise to the level of what is required by existing case law to be in an inherent disclosure. A claim limitation is inherent in the prior art if it is necessarily present in the prior art, not merely probably or possibly present. Rosco v. Mirro Lite, 304 F.3d 1373, 1380, 64 USPQ2d 1676 (Fed. Cir. 2002). This is another general principle of patent law that transcends individual application facts, and clearly requires that for something to be inherently disclosed, that something cannot be just possibly disclosed (as alleged in this portion of the Examiner's Answer to be the case

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regarding Heitritter's disclosure of the claimed predictability feature), and cannot just be probably disclosed (even this degree of disclosure is not alleged in the Examiner's Answer), but must necessarily be disclosed (and this level of disclosure is clearly not alleged in this portion of the Examiner's Answer).

- 5. The Examiner's Answer, on page 12, then speculates, with absolutely no evidence to support the speculation, that "[B]y practicing the reference of the invention, and setting forth the data obtained, based on scientific reasoning, an equation and thus a system of predictably achieving a nutrient level in an end product is arrived at." Unfortunately, the Examiner's Answer fails to point out where the prior art disclosed this conclusion. Appellants respectfully submit that the reason for this is that the prior art does not contain any such disclosure. Only Appellants' Application discloses the claimed invention.
- 6. In the paragraph bridging pages 12 and 13, the Examiner's Answer further speculates (with no prior art evidence presented in support thereof) that by practicing the reference of the invention (presumably, Heitritter), and setting forth the data obtained, based on scientific reasoning, such an equation can be arrived at for predicting nutrient levels in an end product as claimed. Unfortunately, again, the Examiner's Answer fails to point out where the prior art (presumably, Heitritter) contains any disclosure or suggestion of how to arrive at the claimed invention. The reason for this is that the prior art does not contain any such disclosure. Only Appellants' Application discloses the claimed invention.

Appellants disclosure contains an empirical formula for the prediction of the percentage of UIP/RUP based on the temperature the end product attains during the drying procedure. The

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Examiner admits that Heitritter does not disclose this empirical formula and does not predict a quantitative nutrient values based on that formula, but that Heitritter somehow inherently discloses this. In an attempt to explain how Heitritter inherently discloses this, the Examiner uses an analogy. The analogy is that the law of gravity can be explained in terms of a definition or in terms of examples, i.e., gravity can be demonstrated by either the dropping of a pencil or to a formula that will calculate the result.

Unfortunately, Heitritter does not disclose any formula for the prediction of RUP and because Heitritter presents data for only one point, that being the non-predictable 69.9% of the CP, basis for a formula is not disclosed. Furthermore, the Examiner fails to provide objective factual evidence of exactly what the analogous non-empirical formula basis in Heitritter is that discloses the claimed invention, despite having the burden to do so.

Appellants respectfully submit that a fair, balanced review of Heitritter reveals that Heitritter has no clue whatsoever of how to arrive at the claimed invention and the only clue to arrive that exists in the record of this Application is Appellants' disclosure. In other words, this rejection is improperly based on hindsight reconstruction of Appellants' disclosure based solely on Appellants' disclosure.

7. On pages 13 and 14, the Examiner's Answer states that one of ordinary skill in the art would be properly motivated to modify Heitritter to include wet end corn fermenters grain in the corn and soybean meal because of the benefits of wet end fermenters grain as taught by Schingoethe. Unfortunately, the Office Action does not establish that Schingoethe's generic historical disclosure would enhance the nutrient source. Moreover, Appellant respectfully disagrees with the conclusion that one of ordinary skill in the art would be properly motivated to

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modify Heitritter to include wet end corn fermenters grain in the corn and soybean meal because of the benefits of wet end fermenters grain as taught by Schingoethe for the following reasons.

Firstly, Schingoethe's disclosure would actually reduce the nutrient levels of its starting material because the hulls it adds are very much inferior in nutrient levels compared to soybean meal. As example of this, consider that soybean meal is about 48% crude protein and soybean hulls are only about 10% crude protein. Mixing the two will result in a product that is below 48% crude protein. Therefore, one of ordinary skill in the art will not be properly motivated to modify Heitritter in view of Schingoethe, as suggested. Moreover, even if Heitritter is modified regarding mixing of ingredients in view of Schingoethe, as suggested, Heitritter still will not make a mixed product that will have enhanced nutritional values for the reason stated above.

Secondly, Appellants respectfully submit that following Heitritter's teachings will never result in the claimed invention, which recites adding nutrient values to its starting material, because Heitritter never adds any nutrient values to his starting product to increase its nutrient value before heating it or adding water to it, as claimed. In this regard, the Office Action continues to fail to provide objective factual evidence that one of ordinary skill in the art would be properly motivated to modify Heitritter to add any nutrients to his starting product to increase its nutrient value, especially where Heitritter's starting material already has reasonable levels of nutrient values.

Thirdly, because Heitritter does not render the claimed invention obvious for the numerous reasons discussed above and in the Appeal Brief, even if, solely for the sake of argument, one of ordinary skill in the art were properly motivated to modify Heitritter in view of Schingoethe, a suggested, the resulting so-modified version of Heitritter would not disclose, suggest, or otherwise render obvious, the claimed invention.

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Fourthly, Heitritter's invention requires three key components: an oil seed meal, hulls and water. Heitritter states that the oil seed meal can be any proteinaceous feed material suitable for ruminant animal feeding, including soybean meal, corn meal, wheat, barley, oats, etc. However, Appellants' claimed starting materials are not disclosed by Heitritter. Appellants use the by-products, either wet spent grains or solubles, from distillers, brewers or fermenters grains. These products are used as the base ingredients to which are added other protein sources to obtain a mixture having a known quantitative amount of crude protein and amino acid content. In Heitritter's provided example, soybean meal is used as one of the protein sources. Corn meal, wheat, barley, oats and hulls, as used by Heitritter, are specifically not used and would not be appropriate for Appellants' invention. In fact, the use of corn meal, wheat, barley, oats and hulls in the Haschen invention would be detrimental to the end product. In this regard, Appellants respectfully submit that Soybean meal contains about 48-50% crude protein and thus when diluted with the addition of soybean hulls, the crude protein is reduced to about 45-46% as taught by Heitritter. If a material such as corn meal (ground corn grain) as alleged by the Examiner, with a crude protein of 8-9% is diluted with the hulls from the grain, the end product would be lowered to 7-8% crude protein. This low protein content makes the corn grain an undesirable protein feed material to use in ruminant rations (Contrary to Heitritter saying he can use it to any protein source). So the assertion by the examiner that it would be obvious to use corn meal is counterintuitive to one of ordinary skill in the art. Heitritter focuses on soybean meal & actually lowers the crude protein by putting in the hulls to get his fiber/protein balance. In Heitritter's process, the hulls are mixed with the soybean meal in a ratio from 1 to 10% by weight until an ideal "fiber/protein feed balance" is achieved. Heitritter does not add corn meal to soybean meal in his patent. The addition is strictly hulls.

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Fifthly, Heitritter has other differences and features which teach away from arriving at Appellants' claimed invention. For starters, Heitritter indicates that soybean meal is ideal candidate for his feed. It is not an ideal candidate for Appellants' claimed invention, for reasons discussed above. Additionally, in Heitritter, water is added to the mixture until the moisture content is between 30 to 50% by weight. The mixture is then cooked until the wet feed materials reach a temperature of 200F. (Cooker is up to 220) It will take hours to get the product to 200 – evaporative losses cannot exceed the boiling point of water & it will cool the mixture down. At this point it will have a moisture content of about 20 to 25% by weight, as disclosed. As a result Heitritter's process will have in a lot of evaporative loss. Moreover, after the cooking, the moist feed is dried using a rotary drier or other suitable drying equipment. The moisture is reduced to about 12 to 16% and then the hot dry feed is put through a cooler before storage in a bin. Unfortunately, the Office Action does not address these characteristics of Heitritter or take them into account on the record in the rejection, which is another reason why the final Office Action fails to make out a prima facie case of obviousness of the claimed invention.

Also, Heitritter's process is for increasing the UIP/RUP of the soybean meal. Heitritter's examples disclose an outcome of about 69.9% RUP. Heitritter only has one example in his whole disclosure. Furthermore, Heitritter does not enhance the nutrient content of the mixture by the addition of the hulls to the soybean meal – as pointed out above. Heitritter actually reduces the nutrient content of the soybean meal. Additionally, Heitritter does not teach of improving anything other than the RUP, and no predictably of the resulting RUP increase is disclosed or suggested through the cooking of the mixture. The Office's suggestion that it would be obvious for Heitritter to add corn meal to its starting product is refuted by the fact that Heitritter does not add any corn meal (or other corn product) to the soybean meal. He just adds hulls to get the

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fiber/protein balance. The suggestion that corn meal should be added is nothing but speculation devoid of any factual evidence that one or ordinary skill in the art would be properly motivated to do so Heitritter states that the only addition to the starting feed is the hulls of the feed material.

It should be noted that the Examiner's Answer, on page 6, indicates that the claim language "about" is not defined by Heitritter, and that the claimed temperature ranges are disclosed by Heitritter. However, Appellants respectfully disagree and respectfully submit that regarding temperatures of the cookers and dryers, Haschen discloses the dryer temperature as from 200-1000F, whereas the Heitritter patent gives the cooker a temperature of 150 – 220F and a dryer temp of 100 – 150F. Haschen patent gives the temperature of the end product as 208-210, 211-220 and 218F. Heitritter gives the cooker temp for the product as 200F. Moreover, for detailed reasons provided below, the office Action fails to provide objective factual evidence that Heitritter reaches a product temperature above 200 degrees F.

Sixthly, Heitritter does <u>not</u> pre-determine quantitative levels of crude protein, UIP/RUP, amino acids and post ruminal digestibility in the end product, as claimed. Heitritter only does post production analysis of the product to measure an achieved value, but Heitritter does not disclose of any way to predict quantitative nutrient values of an end product. He just discloses that he can increase UIP/RIP in general and only gives one example of this.

Seventhly, Heitritter actually teaches away from the claimed invention by limiting its cooking conditions so that a product temperature above 200 degrees F is not achieved, which is a product temperature that will not result in the claimed invention. For example Heitritter's cooking temperature of 200F (using an oven temperature of 220 degrees F) is consistent with that which can be achieved with a very wet material, e.g., a moisture content of 30 to 50%. The Office has not provided any objective factual evidence that it is even possible impossible to

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increase the temperature of Heitritter's material beyond the boiling point of water using Heitritter's disclosure, and fails to provide objective factual evidence that one of ordinary skill in the art would be motivated to do so. Based on Appellants disclosed experiments that involve comparable water content starting materials, Heitritter will never be able to achieve a cooked product temperature above 200 degrees F. For example, for data in certain of Appellants disclosed charts, e.g., Tables 8 and 9 disclose an end temperature for the end product of 195 degrees F for the first treatment in the experiment after heating in an open vessel for 2 hours at a temperature of 350 degrees F (vessel temperature is given in tables 10 & 11). The starting material in this treatment had a moisture content of 50.522% (disclosed in table 13) and the end product after 2 hours of heating had a moisture content of 29.3% (disclosed in table 12). Other treatments listed in these tables show that much higher cooker temperatures of 450 to 500 degrees F were necessary to reduce the moisture content of the end product and to achieve the highest values for UIP/RUP. If these experiments of Appellants did not raise the temperature of the product to temperature levels above 200 degrees F using a cooker at 350 degrees F, then Heitritter does not provide evidence that it did, either. At the product temperatures achieved by Heitritter, Heitritter's product can never render the claimed invention obvious. Furthermore, after Heitritter's cooking stage the feed material is transferred to a dryer which is operated within a temperature range of 100 to 150F. Thus Heitritter fails to disclose that the feed product will ever exceed the temperature of 200F, which it previously reached in the cooker. The data found in tables 8 and 9 of Appellants' Application clearly show that a starting material with a moisture content of 50.522%, which has a moisture content similar to that of Heitritter's starting product, will not reach a end product temperature over 200 degrees F unless the heating vessel temperature is operating in a range of 450 to 500 degrees F. End product temperatures increased

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in Appellants' disclosed experiment to levels above 200 degrees F when higher heating vessel temperatures were used and the moisture level decreased to levels below 25% by weight. In Appellants' Application, paragraph [0055], it is stated that the product would increase temperature rapidly until it reached a temperature of 208 to 210 degrees F and the product temperature would remain at this temperature for 2 hours or more until the moisture levels were reduced. Appellants respectfully submit that one of ordinary skill in the art realizes that the evaporative cooling effect of the moisture, which leaves the product as steam, prevents the temperature of Heitritter's product from exceeding the boiling point of water at 212 degrees F. Appellants respectfully submit that this was not take into consideration by the Office, but should be. Furthermore, with a vessel temperature of 350 degrees F, evaporative cooling prevents the product from rising above 195 degrees F. Heitritter uses a cooker temperature of 220 degrees F to heat their wet product to a temperature of 200 degrees F. No disclosure of time required to achieve this temperature is given. With the cooker temperature of 220 degrees F and a starting moisture of 30 - 50%, the Office Action fails to demonstrate that the end product in Heitritter method ever exceeds 200 degrees F, and one of ordinary skill in the art would not expect it to do so. Heitritter then sends the cooked material which has a moisture content of 21 to 26% to a dryer that operates at a temperature of 100 - 150 degrees F. Therefore, in Heitritter's whole process there is no reasonable basis for concluding that the temperature of the product ever exceeds 200 degrees F.

In fact, Appellants respectfully submit that Heitritter differs substantially from Appellants; claimed invention, as further explained in the following paragraphs:

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- a). Appellants use a much higher dryer temperature of 200-1000F than does Heitritter. By adjusting the temperature and time of exposure, the product temperature can be controlled to the pre-determined levels needed to achieve desired and predicted RUP levels.
- b) Appellants' disclosure presents data is from an experiment in which the wet mixture of corn distillers grains and soybean meal were dried in a controlled manner. A temperature probe was inserted into the wet mass as it was dried by application of heat. The process was stopped at various temperature points and samples were sent for analysis of the UIP/RUP and digestibility. Results of this experiment reported in Table 8 of the patent are given below:

End	UIP% CF
<u>Temp</u>	Average
195	53.68
218	74.50
229	82.93
208	65.87
218	67.48
209	62.07
214	65.32
208	63.31
214	62.75

- c). Regression analysis of this data this data revealed that 85.6% of the variation in UIP of the end product was due to the temperature of the material. The statistics showed a significance of P< 0.0003, meaning that the probability of this result happening is extremely high.
- d). From this regression analysis, an equation to predict UIP/RUP from the end temperature of the feed mix was available.

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UIP (% of CP) = (End Product Temperature  $^{\circ}$ F x 0.819) - 107.644

- e). Using this equation to predict the UIP of Heitritter's product with a temperature of 200F will yield a value of 56.16%. This is much lower than Heitritter's reported value of 69.9% and thus we must assume that Heitritter's procedure and/or starting product and end product are very different than that of Haschen et al. and would not render obvious the claimed invention.
- f). Appellants respectfully submit that the Examiner must consider this comparative data in Applicants' application, which illustrates the claimed invention in reaching a conclusion with regard to obviousness or non-obviousness of the claimed invention. See, in this regard, *In re Margolis*, 785 F.2d 1029, 228 USPQ 940 (Fed. Cir. 1986), as set forth in MPEP §716.01(a).
- 8. Appellants respectfully submit that one of ordinary skill in the art would not be properly motivated to turn to Schingoethe to modify Heitritter as suggested in the Examiner's final Office Action or in the Examiner's Answer for at least the following reasons:
- a) Schingoethe, the secondary reference, describes a number of experiments in which either wet corn distillers grains or dry distillers grains were fed as a protein source to lactating dairy cows as compared to feeding soybean meal as the protein. The experiments he reports show that milk production performance of the cows, was greater when the corn distillers (wet or dry) was fed as compared to soybean meal. Given this finding it does not seem logical for one or ordinary skill in the art of feeding cattle to combine these two feedstuffs in an irreversible mixture.
- b) Schingoethe and other researchers suspected the amino acids lysine and methionine may not be sufficient in the corn distillers grains and thus an addition of ruminally

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protected lysine and methionine was made to the total ration of the cows in two of the experiments. Results are mixed, with one experiment showing a small increase in milk production, and another showing less milk. Again there is no motivation found in Shingoethe for one of ordinary skill in the art to change the amino acid levels found in the corn distillers grains.

- c) Schingoethe goes on in his presentation to talk about experiments by Polan et al. (1991) in which corn gluten meal (a 60% crude protein by-product of the starch industry that has a RUP levels as high as 70% of the CP) when compared to feeding soybean meal to lactating cows resulted in lower milk production. In these experiments ruminally protected lysine and methionine were also added with no effect. Again this disclosure would not motivate one of ordinary skill in the art to add more amino acids, e.g., lysine and/or methionine, to a feed protein for dairy cattle.
- d) Schingoethe also describes an experiment by Liu et al. 2000 in which a ration with corn distillers grains as the source of protein was compared to one using a mix of 25% corn distillers grains, 25% fish meal and 50% soybean meal. Theoretical evaluations of the ration using the protein blend showed it to contain a more desirable array of amino acids and it should have supported greater milk production than the corn distiller grains diet. However, production was not increased by use of the protein blend. Again this disclosure would not motivate one of ordinary skill in the art to combine various protein sources.
- e) Schingoethe does not teach methods of increasing the UTP/RUP of a feed protein. Schingoethe's presentation shows that corn distillers grains, wet or dry, can make up all the supplemental protein in the dairy ration and the cows will produce more milk than when soybean meal is the sole protein source. Heitritter shows a method for increasing the RUP of soybean meal. Considering that wet corn distillers is already moderately high in RUP, 47% in

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Schingoethe's paper, there is no reason to further process the wet distillers grains to achieve a higher RUP. Schingoethe makes no reference to attempting to alter the RUP of wet distillers grain or mixing it with other protein sources. His research was directed to proving the efficacy of wet distillers grains verses soybean meal. With this information, one of ordinary skill in the art would not conclude that the two ingredients should be mixed or that there would be any nutritional advantage in mixing the two.

- 9. On page 16, the Examiner's Answer states that it is unclear where the Office made the statement that it is not equipped to manufacture products and thus the burden has been shifted to Appellant to show that the claimed products are different. In this regard, Appellants note that this position appears in page 7 of the final Office Action mailed on May 31, 2006. If that action is not incorporated by reference in the outstanding final Office Action, then it is moot.
- 10. Concerning Amino Acid levels: The Examiner's Answer states "Specifically regarding the levels of amino acids levels, in the absence of a definition with the limitations of the term "about", the ranges of amino acids taught by Heitritter of 3.8% lysine and 12.8% methionine read upon appellant's claimed ranges of about 2% lysine and about 8% methionine. Furthermore, it would have been obvious to vary the amino acid levels of lysine and methionine in the feed composition depending on the particular cattle to which the feed was produced, i.e. feed for a lactating cattle would have different requirements than feed for meat cattle."

In response to these arguments, the Examiner's Answer appears to have reversed the lysine and methionine percentages. Heitritter gives values of 12.8 g/kg lysine and 3.8 g/kg methionine digestible bypass amino acid per kg of product. The values from the Haschen patent application are given as lysine greater than 2% and up to 8% of the RUP protein and methionine

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greater than 1% and up to 2% of the RUP protein. Additionally, the values given by Heitritter are

not percentages but are grams per kilogram. His numbers would have to be divided by 10 to

convert to a percentage. Thus Heitritter gives the numbers of 1.28% lysine and 0.38%

methionine in the total product.

Appellants respectfully submit that one of ordinary skill in this art, including Schingoethe

and other researchers, suspected the amino acids lysine and methionine may not be sufficient in

the corn distillers grains and thus an addition of ruminally protected lysine and methionine was

made to the total ration of the cows in two of the experiments. However, the results are mixed

with one experiment showing a small increase in milk production and another showing less milk.

Accordingly, there is no motivation for one trained in the art to change the amino acid levels

found in the corn distillers grains.

11. Appellants respectfully submit that the conclusion, e.g., on page 8 of the

Examiner's Answer, that one of ordinary skill in the art would have been motivated to include a

combination of wet end corn fermenters grains and high protein soybean/corn meal as the

composition of the feed material based on Heitritter in view of Schingoethe, is without merit for

a number of reasons...

Firstly, Schingoethe describes a number of experiments in which either wet corn distillers

grains or dry distillers grains were fed as a protein source to lactating dairy cows as compared to

feeding soybean meal as the protein. The reported experiments show that performance of the

cows, i.e. milk production, was greater when dry corn distillers was fed and as good as when wet

corn distillers was fed as compared to soybean meal. Given this finding it does not seem logical

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for one trained in the art of feeding cattle to combine these two feedstuffs in an irreversible mixture.

Secondly, the Examiner's Answer states: "Schingoethe teaches that the inclusion of wet end fermenters grain, in feed for lactating cattle, has been known for several years. Schingoethe teaches that corn distiller's grain is a good quality protein source. Schingoethe teaches animal performance is better when cattle are feed wet corn distiller's grain as opposed to dry corn distiller's grain. Schingoethe teaches that corn gluten meal (corn after the starch and germ have been removed) is a very good protein supplement, but is best when fed in combination with other protein supplements. Refer specifically to page 1 paragraph 1, page 3 paragraph 3, page 4 paragraph 1, and page 5 paragraph 3 of Schingoethe."

Thirdly, Schingoethe states on page 2 paragraph 1 "[I]n experiments that compared CDG (corn distillers grains) to soybean meal as the protein supplements, production was similar (Schingoethe et al, 1983; 1989; 1999) when fed wet CDG or higher (Nichols et al, 1998) when fed dried CDG than when fed soybean meal." From this statement it is obvious that Schingoethe means that dairy cattle performance is better using dried CDG as compared to wet CDG. Schingoethe goes on to say "When fed lighter colored dried CDG plus solubles from whiskey or from fuel-ethanol preparations, production was higher (P<0.05) than when fed soybean meal (Powers et al., 1995)." On page 3 paragraph 2, he states "I am not aware of any trials with lactating cows that directly compared wet versus dried CDG."

Fourthly, the Examiner[s Answer states that "Heitritter in view of Schingoethe teach of a similar base nutrient composition and an end product with similar nutrient values as appellant." Appellants respectfully disagree, and point out that Heitritter demonstrates only one end product that is not made of the same materials as the Haschen patent. Schingoethe does not produce any

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mixed ingredient products; and only teaches of experiments feeding different forms of ingredients.

Fifthly, Schingoethe does not teach methods of increasing the UIP/RUP of a feed protein. Schingoethe's paper shows that corn distillers grains, wet or dry, can make up all the supplemental protein in the dairy ration and the cows will produce more milk than when soybean meal is the sole protein source. Heitritter shows a method for increasing the RUP of soybean meal. Considering that wet corn distillers is already moderately high in RUP, 47% in Schingoethe's paper, Appellants respectfully submit that one of ordinary skill in the art would not have proper incentive to further process the wet distillers grains to achieve a higher RUP, nor would one trained in the art would conclude that the two ingredients should be mixed and then processed to increase the RUP. Appellants respectfully submit that, to one trained in the art of feeding dairy cattle, there would be no proper motivation to include wet or dry corn distillers grains with soybean meal as neither Heitritter nor Schingoethe suggest such a product. In fact, because animal performance is the same (wet CDG) or better (dry CDG) than with soybean meal would lead one to use the CDG products and eliminate the soybean meal altogether. Nor does the applied art provide any motivation to vary the ratio of these ingredients to obtain specific concentrations of protein.

Sixthly, Schingoethe also describes an experiment by Liu et al. 2000 in which a ration with corn distillers grains as the source of protein was compared to one using a mix of 25% corn distillers grains, 25% fish meal and 50% soybean meal. Theoretical evaluations of the ration using the protein blend showed it to contain a more desirable array of amino acids and it should have supported greater milk production than the corn distiller grains diet. However, production was not increased by use of the protein blend. In view of this, one trained in the art would not be

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motivated to combine various protein sources as suggested in the final Office Action and in the Examiner's Answer.

Schingoethe also discusses about experiments by Polan et al. (1991) in which corn gluten meal (a 60% crude protein by-product of the starch industry that has a RUP levels as high as 70% of the CP) when compared to feeding soybean meal to lactating cows resulted in lower milk production. In these experiments ruminally protected lysine and methionine were also added with no effect. Appellants respectfully submit that this would not motivate one trained in the art to add more amino acids, i.e. lysine and/or methionine, to a feed protein for dairy cattle.

Seventhly, Schingoethe talks about the performance of corn gluten meal (60% crude protein, which is not to be confused with corn gluten feed or corn distillers grains) as being inferior when compared to feeding soybean meal. Adding ruminally protected lysine and methionine did not correct the problem.

Eighthly, Schingoethe does state further on that corn gluten meal should be fed in combination with other proteins, i.e. it should not be fed as the sole source of protein. However, neither the final Office Action nor the Examiner's Answer has presented objective factual evidence to demonstrate that this disclosure, which is based on corn gluten meal, would apply to corn distillers grains to motivate one of ordinary skill in the art to modify Heitritter in view of Schingoethe, as suggested.

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#### **CONCLUSION**

For the reasons presented in the Appeal Brief and in this Reply Brief, Appellants respectfully submit that the outstanding rejections of record are without merit and should be reversed.

If necessary, the Commissioner is hereby authorized in this, concurrent, and future replies to charge payment or credit any overpayment to Deposit Account No. 02-2448 for any additional fees required under 37 C.F.R. §§ 1.16 or 1.17, particularly extension of time fees.

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Respectfully submitted,

RJW:mmi/jmc

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